Application No.: 10/805,028

Reply to Office Action of: 12/12/2006

<u>CLAIMS</u>

The current claim set of the application is presented below. Indications as to the status of the claims ("original", "currently amended", "cancelled", "new", etc.) appear in parentheses after the claim number. Deletions are identified in bold with double brackets and strikethrough (e.g. [[deletion]]) and new text is identified in bold with underlining (e.g. new language).

What is claimed is:

I. (Currently Amended) A kit comprising a needle and an implantable lead for stimulation of nerve tissue, muscle or organs, wherein the implantable lead is adapted to be passed through the needle; the lead comprising:

an elongate lead body having an axis and a tip; and

- at least one extendable member having a distal portion adapted to curl upon itself when not-constrained to form an electrode and a proximal portion, the extendable member received at least in part within the lead body for axial movement between:
 - a retracted position in which the distal and proximal portions are constrained within the lead body; and
 - an extended position in which the proximal portion is retained within the lead body and the distal portion is deployed out the tip of the lead body such that the distal portion curls <u>tightly</u> upon itself <u>to form a compact electrode</u>.
- 2. (Original) The kit of claim 1 in which the extendable member further comprises an intermediate portion between the distal and proximal portions.
- 3. (Original) The kit of claim 2 in which the intermediate portion is deployed out of the lead body when the extendable member is in the extended position.
- 4. (Original) The kit of claim 2 in which the intermediate portion comprises an insulated wire allowing current to flow between the proximal portion and the distal portion.

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- 5. (Original) The kit of claim 2 wherein the intermediate portion is adapted to curl as it is deployed out the tip of the lead body less tightly than the distal portion curls upon itself.
- 6. (Original) The kit of claim 5 in which the distal portion is formed such that it tends to curl upon itself in two dimensions in the extended position.
- 7. (Original) The kit of claim 5 in which the distal portion is formed such that it tends to curl upon itself in three dimensions in the extended position.
- 8. (Original) The kit according to claim 1, wherein the extendable member comprises wire, and the distal portion comprises one or more external coiled conductors.
- (Original) The kit according to claim 8 wherein the one or more external coiled conductors
 comprises a plurality of external coiled conductors having dissimilar properties.
- 10. (Original) The kit according to claim 1, wherein the distal portion of the extendable member has preset elastic properties that tend to cause the distal portion to curl into an electrode.
- 11. (Original) The kit according to claim 1, wherein the distal portion of the extendable member is formed of bimetallic metals or nitinol material that change shape due to temperature changes.
- 12. (Original) The kit according to claim 1, wherein the distal portion of the extendable member will uncurl if the extendable member is retracted into the lead body.
- 13. (Original) The kit according to claim 1, wherein the distal portion of the extendable member is sufficiently flexible that the distal portion will uncurl if the entire lead body is pulled through tissue, thereby reducing trauma to the tissue if excessive forces are applied to the lead.

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- 14. (Original) The kit according to claim 1, wherein the extendable member has a preset curve so that as it is extended axially beyond the lead body, it will move also in directions laterally to the axis of the lead body.
- 15. (Original) The kit according to claim 14, wherein the extendable member has a preset curve over the distal portion.
- 16. (Original) The kit according to claim 14, wherein the extendable member has an elasticity that allows it to be held straight by the lead body but allows the extendable member to resume its preset curve when it is extended beyond the tip of the lead body.
- 17. (Original) The kit according to claim 14, wherein the extendable member has a preset curvature such that, when deployed out of the lead body, the extendable member moves in axial directions and lateral directions.
- 18. (Original) The kit according to claim 14, wherein the extendable member has a preset curve so that as it is extended beyond the lead body, it will move also in directions perpendicular to the axis of the lead body.
- 19. (Original) The kit according to claim 1, wherein the extendable member is held by the lead body against rotation relative to the lead body.
- 20. (Original) The kit according to claim 19 in which the extendable member has an asymmetric cross section along at least a portion of the proximal portion thereof, the lead body having a channel receiving at least the proximal portion, the channel having an asymmetric cross section that engages the asymmetric cross section of the extendable member to hold the extendable member against rotation relative to the lead body.
- 21. (Original) The kit according to claim 1, wherein the extendable member comprises a plurality of extendable members, each of which can be independently extended to deploy a distal portion beyond the tip of the lead body.

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22. (Original) The kit according to claim 1, wherein the lead body has a diameter, and the electrode formed by curling of the distal portion has a 2- or 3-dimensional shape in which one or more of the dimensions is larger than the diameter of the lead body.

- 23. (Original) The kit according to claim 1, wherein the lead body has a central portion movable axially within the lead body to move the at least one extendable member between the retracted and extended positions.
- 24. (Original) The kit according to claim 1, in which the extendable member comprises a plurality of extendable members, wherein the distal portions of the extendable members can be selectively deployed such that the electrodes fit a surface of tissue or achieve a desired distribution of current.
- 25. (Original) The kit according to claim 1, wherein the distal tip of the extendable member has a material coating adapted to keep the distal tip straight after deployment past the tip of the lead body, wherein the material will dissolve over time inside the body.
- 26. (Original) The kit of claim 25, wherein the material coating will dissolve by application of electrical current through the distal portion of the extendable members.
- 27. (Original) The kit according to claim 1, wherein the extendable member is small enough to pass through a small body lumen, the distal portion being adapted to be advanced through the small body lumen and to curl into an electrode after being advanced through the small body lumen.
- 28. (Currently Amended) A method of implanting an implantable lead for spinal cord or sacral nerve stimulation, the method comprising:

percutaneously placing a needle for delivery of a lead to a desired location;

passing an implantable lead through the needle, the implantable lead having an elongate lead body having an axis and a tip; and at least one extendable member having a

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distal portion adapted to curl upon itself when not-constrained and a proximal portion, the extendable member received at least in part within the lead body for axial movement between:

- a retracted position in which the distal and proximal portions are constrained within the lead body and
- an extended position in which proximal portion is retained within the lead body and the distal portion is deployed out the tip of the lead body such that the distal portion curls tightly upon itself to form a compact electrode; and extending the distal portion of the extendable member out the tip of the lead body to advance the distal portion through the foramen and to allow the distal portion to curl tightly upon itself to form [[##]] a compact electrode on other side of the foramen from the lead body.
- 29. (Original) The method of claim 28 in which the desired location is an epidural space dorsal to the spinal cord.
- 30. (Original) The method of claim 29 further comprising inserting the implantable lead adjacent a foramen or bony canal.
- 31. (Original) The method of claim 28 further comprising inserting the implantable lead adjacent a foramen or bony canal.
- 32. (Original) The method of claim 31 in which the foramen is an intervertebral foramen.
- 33. (Original) The method of claim 31, wherein the foramen is a sacral foramen.
- Original) The method of claim 32, wherein the foramen is the foramen rotundum.